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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants   : Joerg Kaufmann et al.

Application No. : 09/758,575

Filed   : January 9, 2001

10   For   : GENES DIFFERENTIALLY EXPRESSED IN BREAST CANCER

Examiner   : Alana M. Harris

Art Unit   : 1642

Docket No. : 59516-216/PP-01656.002

Date   : August 29, 2005

15   Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT OF DR. CHRISTOPH REINHARD UNDER 37 C.F.R. § 1.132

20   Sir:

I, Dr. Christoph Reinhard, being duly sworn, say:

1.   I am a true and original inventor of the claimed subject matter of the above-identified patent application.

25   2.   I am an internationally recognized scientist and am presently employed as a Project Leader at Chiron Corporation, Emeryville, California (Employed at Chiron from 1995 to present). I received a Bachelors Degree in Human Genetics from the

Universitat Frieburg and a Ph.D. degree from the Friedrich Miescher Institute in Biochemistry.

3.   I am an author or co-author of more than 17 peer-reviewed research articles and have been invited to give numerous presentations on my research at national and international meetings.

4.   In my capacity as a biochemist and molecular biologist, I am familiar with measuring expression of genes and proteins in cells and tissue samples, using methods well-known to those of ordinary skill in the art at the time of filing of the above-identified patent application.

5.   I understand that claims of the above-referenced patent application are rejected under 35 U.S.C. § 112, first paragraph, on the grounds that one skilled in the art would not know how to use the claimed invention, because the claimed invention is allegedly not enabled. I generally understand that enablement refers to whether one skilled in the art can make and/or use the invention as claimed. I understand that the Examiner questions the applicability of SEQ ID NO:2 to diagnostic methods relative to breast cancer.

6.   This concern is addressed by the results of experiments using tissue samples from metastatic breast cancer, primary breast cancer, and normal breast tissue samples. hsOAF antisera were generated in two rabbits immunized against the C-terminal peptide (H-FYVPQRQLCLWDEDPYPG-OH, KLH conjugated), and affinity purification was conducted to obtain OAF polyclonal antibody. Immunohistochemical staining was performed using staining kits from BioGenex Laboratories, Inc. (San Ramon, CA), using the manufacturer's protocol. Using this immunohistochemical staining technique with antibody to hsOAF, strong expression of hsOAF (SEQ ID NO:2) was detected in 26 out of 26 metastatic tissue samples and 44 out of 45 primary breast tumor tissue samples. However, only weak staining was seen in 8 out of 24 normal breast tissue samples.

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7.   Therefore, a person of ordinary skill in the art would reasonably conclude that the present invention demonstrates a functional relationship between hsOAF expression and the cancer phenotype.   The data disclosed herein confirms this relationship using human tissue samples.

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8.   I further declare that all statements made herein of my own knowledge are true and that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

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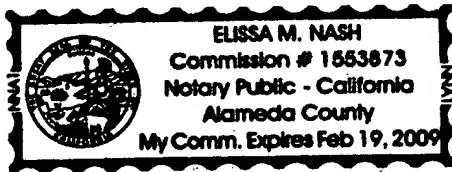Christoph Reinhard

State of California)

) ss.:
15   County of Alameda)

       On this 8\23\05 day of July, 2005, before me, a Notary Public in and for the State and County aforesaid, personally appeared Christoph Reinhard, to me known and known to me to be the person of that name, who signed and sealed the foregoing
20   instrument, and he acknowledged the same to be her free act and deed.

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Notary Public

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Commission expires 2\19\09

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